

### Subpart C—Cholecystokinetic Drug Products

#### § 357.201 Scope.

(a) An over-the-counter cholecystokinetic drug product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this subpart in addition to each of the general conditions established in § 330.1.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

[48 FR 27005, June 10, 1983]

#### § 357.203 Definition.

As used in this subpart:

*Cholecystokinetic drug product.* A drug product that causes contraction of the gallbladder and is used during the course of diagnostic gallbladder studies (cholecystography).

[48 FR 27005, June 10, 1983]

#### § 357.210 Cholecystokinetic active ingredients.

The active ingredient of the product consists of any of the following when used within the specified concentration and dosage form established for each ingredient:

(a) 50-percent aqueous emulsion of corn oil.

(b) Hydrogenated soybean oil in a suitable, water-dispersible powder. The hydrogenated soybean oil is food-grade, partially hydrogenated with a melting point of 41 to 43.5 ° C, an iodine value of 65 to 69, and a fatty acid composition as follows:

Fatty acid	Percent composition
Myristic acid .....	0.1
Palmitic acid .....	10.0
Palmitoleic acid .....	0.1
Stearic acid .....	13.5
Oleic acid .....	72.0
Linoleic acid .....	3.8
Linolenic acid .....	0.1
Arachidic acid .....	0.5
Behenic acid .....	0.2

[54 FR 8321, Feb. 28, 1989]

#### § 357.250 Labeling of cholecystokinetic drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a "gallbladder diagnostic agent."

(b) *Indications.* The labeling of the product states, under the heading "Indications," the following: "For the contraction of the gallbladder during diagnostic gallbladder studies." Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph (b), may also be used, as provided in § 330.1(c)(2), subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Warnings.* [Reserved]

(d) *Directions.* The labeling of the product contains the following statements under the heading "Directions":

(1) "Take only when instructed by a doctor."

(2) *For products containing 50-percent aqueous emulsion of corn oil.*

(i) "Shake well before using."

(ii) Oral dosage is 60 milliliters 20 minutes before diagnostic gallbladder x-ray or as directed by a doctor.

(3) *For products containing hydrogenated soybean oil.* Oral dosage is 12.4 grams in a suitable, water-dispersible powder in 2 to 3 ounces of water. Stir briskly to prepare a suspension before using. Drink 20 minutes before diagnostic gallbladder x-ray or as directed by a doctor.

(e) The word "physician" may be substituted for the word "doctor" in any of the labeling statements in this section.

[48 FR 27005, June 10, 1983, as amended at 51 FR 16267, May 1, 1986; 52 FR 7830, Mar. 13, 1987; 54 FR 8321, Feb. 28, 1989]

#### § 357.280 Professional labeling.

The labeling provided to health professionals (but not to the general public) may contain the following information for ingredients identified in § 357.210: *Indication.* "For visualization

of biliary ducts during cholecystography.”

[54 FR 8321, Feb. 28, 1989]

## Subparts D–H [Reserved]

### Subpart I—Deodorant Drug Products for Internal Use

SOURCE: 55 FR 19865, May 11, 1990, unless otherwise noted.

#### § 357.801 Scope.

(a) An over-the-counter deodorant drug product for internal use in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this subpart and each general condition established in § 330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

#### § 357.803 Definitions.

As used in this subpart:

(a) *Colostomy*. An external operative opening of the colon.

(b) *Deodorant for internal use*. An ingredient taken internally to reduce odors arising from conditions such as colostomies, ileostomies, or fecal incontinence.

(c) *Ileostomy*. An external operative opening from the ileum.

(d) *Incontinence*. An inability to retain urine or feces.

#### § 357.810 Active ingredients for deodorant drug products for internal use.

The active ingredient of the product consists of either of the following when used within the dosage limits established for each ingredient in § 357.850(d):

(a) Bismuth subgallate.

(b) Chlorophyllin copper complex.

#### § 357.850 Labeling of deodorant drug products for internal use.

(a) *Statement of identity*. The labeling of the product contains the established name of the drug, if any, and identifies the product as a “deodorant for internal use” or as a “colostomy or ileostomy deodorant.”

(b) *Indications*. The labeling of the product states, under the heading “Indications,” any of the phrases listed in paragraph (b) of this section as appropriate. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in paragraph (b) of this section may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *For products containing bismuth subgallate identified in § 357.810(a)*. “An aid to reduce odor from a colostomy or ileostomy.”

(2) *For products containing chlorophyllin copper complex identified in § 357.810(b)*. (i) “An aid to reduce odor from a colostomy or ileostomy.”

(ii) “An aid to reduce fecal odor due to incontinence.”

(c) *Warnings*. The labeling of the product contains the following warnings under the heading “Warnings”: (1) *For products containing chlorophyllin copper complex identified in § 357.810(b)*. (i) “If cramps or diarrhea occurs, reduce the dosage. If symptoms persist, consult your doctor.”

(ii) The warning required by § 330.1(g) of this chapter concerning overdose is not required on products containing chlorophyllin copper complex identified in § 357.810(b).

(2) [Reserved]

(d) *Directions*. The labeling of the product contains the following information under the heading “Directions.”

(1) *For products containing bismuth subgallate identified in § 357.810(a)*. Adults and children 12 years of age and over: Oral dosage is 200 to 400 milligrams up to 4 times daily. Children under 12 years of age: consult a doctor.

(2) *For products containing chlorophyllin copper complex identified in § 357.810(b)*. Adults and children 12 years of age and over: Oral dosage is 100 to 200 milligrams daily in divided doses as required. If odor is not controlled, take